

WHAT IS CLAIMED IS:

1. A reagentless whole-blood analyte detection system capable of being deployed near a patient comprising:
  - a source capable of emitting a beam of radiation comprising a spectral band having a center wavelength;
  - a detector in an optical path of the beam;
  - a housing configured to house the source and the detector; and
  - a sample element situated in the optical path of the beam and configured to be filled with a sample, the sample element comprising:
    - a sample cell wall that does not eliminate transmittance of the radiation in the spectral band; and
    - a sample cell.
2. The whole-blood system of Claim 1, wherein the sample element is configured to be advanced into the housing.
3. The whole-blood system of Claim 1, wherein the sample cell is oriented about vertically.
4. The whole-blood system of Claim 1, wherein the sample cell is oriented about horizontally.
5. The whole-blood system of Claim 1, wherein the sample element comprises a cuvette.
6. The whole-blood system of Claim 1, wherein the sample element comprises a test strip.
7. The whole-blood system of Claim 1, wherein the sample element comprises a disposable test strip.

8. The whole-blood system of Claim 7, wherein the disposable test strip is configured for a single use.

9. The whole-blood system of Claim 7, wherein the disposable test strip is configured for at least one use.

10. The whole-blood system of Claim 1, wherein the near-patient test system is configured to be used by a patient.

11. The whole-blood system of Claim 1, wherein the near-patient test system is configured to be used by a medical practitioner.

12. The whole-blood system of Claim 1, wherein the near-patient test system is configured to be used in a clinical setting.

13. The whole-blood system of Claim 1, wherein the sample element is configured to receive blood that has been withdrawn from the patient but that has not been otherwise processed.

14. The whole-blood system of Claim 1, further comprising a filtering system in the optical path of the beam, the filter system configured to transmit the spectral band of radiation.

15. The whole-blood system of Claim 14, wherein the filtering system further comprises a tunable filter.

16. The whole-blood system of Claim 14, wherein the filtering system is configured to transmit the spectral band of radiation between about 0.8  $\mu\text{m}$  and about 2.5  $\mu\text{m}$ .

17. The whole-blood system of Claim 14, wherein the filtering system is configured to transmit the spectral band of radiation between about 2.5  $\mu\text{m}$  and about 20  $\mu\text{m}$ .

18. The whole-blood system of Claim 14, wherein the filtering system is configured to transmit the spectral band of radiation between about 20  $\mu\text{m}$  and about 100  $\mu\text{m}$ .

19. The whole-blood system of Claim 14, wherein the filtering system is configured to transmit radiation at least at one spectral band between about 3.5  $\mu\text{m}$  and about 14  $\mu\text{m}$ .

20. The whole-blood system of Claim 14, wherein the filtering system is configured to transmit radiation at least at about one of the following center wavelengths: 4.2  $\mu\text{m}$ , 5.25  $\mu\text{m}$ , 6.12  $\mu\text{m}$ , 7.4  $\mu\text{m}$ , 8.0  $\mu\text{m}$ , 8.45  $\mu\text{m}$ , 9.25  $\mu\text{m}$ , 9.65  $\mu\text{m}$ , 10.4  $\mu\text{m}$ , 12.2  $\mu\text{m}$ .

21. The whole-blood system of Claim 1, wherein the sample element comprises an optical pathlength of less than about 1.22 mm.

22. The whole-blood system of Claim 1, wherein the sample element comprises an optical pathlength of less than about 100  $\mu\text{m}$ .

23. The whole-blood system of Claim 1, wherein the sample element comprises an optical pathlength of less than about 80  $\mu\text{m}$ .

24. The whole-blood system of Claim 1, wherein the sample element comprises an optical pathlength between about 1  $\mu\text{m}$  and about 50  $\mu\text{m}$ .

25. The whole-blood system of Claim 1, wherein the sample element comprises an optical pathlength between about 15  $\mu\text{m}$  and about 35  $\mu\text{m}$ .

26. The whole-blood system of Claim 1, further comprising a sample extractor.

27. The whole-blood system of Claim 26, wherein the sample extractor is selected from the group consisting of: a lance, laser lance, single-motion lance, iontophoretic sampler, gas-jet, fluid-jet or particle-jet perforator.

28. The whole-blood system of Claim 26, wherein the sample element further comprises an opening in fluid communication with the sample cell, and the sample extractor is positioned so that it creates a wound proximate the opening.

29. The whole-blood system of Claim 1, wherein the sample cell wall comprises polyethylene.

30. The whole-blood system of Claim 1, wherein the sample cell wall comprises polypropylene.

31. The whole-blood system of Claim 1, wherein the sample cell wall comprises a polymer having an isotactic structure.

32. The whole-blood system of Claim 1, wherein the sample cell wall comprises a polymer having an atactic structure.

33. The whole-blood system of Claim 1, wherein the sample cell wall comprises a polymer having a syndiotactic structure.

34. The whole-blood system of Claim 1, wherein the sample cell wall comprises a material configured to enhance flow of the sample.

35. The whole-blood system of Claim 1, wherein the sample element is configured to be advanced automatically into the housing.

36. The whole-blood system of Claim 1, wherein the sample element is configured to be advanced manually into the housing.

37. An reagentless whole-blood analyte detection system capable of being deployed near a patient comprising:

a radiation generating system comprising a filter and a source capable of generating electromagnetic radiation in at least one spectral band between about 4.2  $\mu\text{m}$  and about 12.2  $\mu\text{m}$ ;

an optical detector positioned in the optical path of the spectral band of radiation responsive to the spectral band of radiation to generate at least one signal;

a signal processor configured to receive the signal, to process the signal and to generate an output;

a display configured to receive the output;

a sample extractor; and

a portable housing configured to house at least partially each of the radiation generating system, the optical detector, the signal processor, and the sample extractor, the housing adapted to house a sample element having at least one optically transmissive portion.

38. The whole-blood system of Claim 37, wherein the sample extractor is selected from the group consisting of: a lance, laser lance, single-motion lance, iontophoretic sampler, gas-jet, fluid-jet or particle-jet perforator.

39. The whole-blood system of Claim 37, wherein the display comprises an audible display.

40. The whole-blood system of Claim 37, wherein the display comprises a visual display.

41. The whole-blood system of Claim 37, wherein the display is a separable device.

42. The whole-blood system of Claim 41, wherein the separable device is a portable computing device.

43. A reagentless whole-blood analyte detection system comprising:

a source configured to emit electromagnetic radiation;

an optical detector positioned in an optical path of the radiation; and

a sample element situated in the optical path of the radiation;

whereby the detection system performs optical analysis on a sample of whole-blood to assess at least one constituent of the whole-blood.

44. The whole-blood system of Claim 43, wherein the sample element is configured to be advanced into the optical path of the radiation.

45. The whole-blood system of Claim 43, wherein the sample cell is oriented about vertically.

46. The whole-blood system of Claim 43, wherein the sample cell is oriented about horizontally.

47. The whole-blood system of Claim 43, further comprising a portable housing configured to house at least partially the source and the optical detector.

48. The whole-blood system of Claim 43, wherein the constituent is glucose in an analyzed concentration.

49. The whole-blood system of Claim 43, wherein the sample element is configured to be advanced automatically into the optical path of the radiation.

50. The whole-blood system of Claim 43, wherein the sample element is configured to be advanced manually into the optical path of the radiation.

51. A reagentless whole-blood detection system capable of being deployed near a patient comprising:

an optical calibration system; and

an optical analysis system;

wherein the optical calibration system is adapted to calibrate the whole-blood system at about the same time that the optical analysis system analyzes the sample of whole-blood.

52. The whole-blood system of Claim 51, wherein the optical calibration system is adapted to calibrate the whole-blood system at the same time that the optical analysis system analyzes the sample of whole-blood.

53. The whole-blood system of Claim 51, wherein the optical calibration system is adapted to calibrate the whole-blood system before the optical analysis system analyzes the sample of whole-blood.

54. The whole-blood system of Claim 51, wherein the optical calibration system is adapted to calibrate the whole-blood testing system after the optical analysis system analyzes the sample of whole-blood.

55. The whole-blood system of Claim 51, wherein the system further comprises:  
a radiation source system capable of generating an analyte transmission beam;  
a detector in an optical path of the analyte transmission beam; and  
a sample element configured to be advanced into the optical path of the analyte transmission beam, the sample element comprising:

an analysis portion having a sample cell that extends between a first window and a second window

56. The whole-blood system of Claim 55, wherein the sample element further comprises a calibration portion and the radiation source system is capable of generating a calibration beam that impinges upon the calibration portion of the sample element.

57. A method of performing whole-blood detection comprising:  
providing a reagentless whole-blood detection system capable of being deployed near a patient, the whole-blood system comprising an optical calibration system, an optical analysis system, and a sample cell;  
filling a substantial portion of the sample cell with a sample;  
taking a first calibration measurement of the sample cell; and  
taking an analytical measurement of a sample of whole-blood in the sample cell.

58. The method of Claim 57 further comprising calibrating the whole-blood system;  
wherein the step of calibrating is performed before the step of filling.

59. The method of Claim 57, further comprising calibrating the whole-blood system;

wherein the step of calibrating is performed after the step of taking an analytical measurement.

60. The method of Claim 57, further comprising taking a second calibration measurement;

wherein the step of taking a first calibration measurement is performed before the step of filling the sample cell and the step of taking a second calibration measurement is performed after the step of filling a substantial portion of the sample cell.

61. The method of Claim 60, further comprising evacuating a substantial portion of the sample cell;

wherein the step of taking a second calibration measurement is performed after the step of evacuating a substantial portion of the sample cell.

62. A method for reagentless whole-blood analyte detection comprising:

providing a source, a detector in an optical path of the source, a housing configured to house the source and the detector, and a sample element comprising a sample cell and an optical pathlength;

drawing a sample of fluid from a portion of tissue;

positioning an opening of the sample element adjacent the sample of fluid so that the fluid is drawn into the sample element;

positioning the sample element in the housing so that the sample cell is in the optical path of the source;

emitting an emitted radiation beam comprising at least one spectral band having a center wavelength from the source to the sample cell of the sample element; and

detecting a transmitted radiation beam comprising the radiation transmitted through the sample element.

63. The method of Claim 62, wherein the housing is configured to be portable.



64. The method of Claim 62, wherein the sample of fluid is a sample of whole-blood.

65. The method of Claim 62, wherein the optical pathlength of the sample cell is less than about 1.22 mm.

66. The method of Claim 62, wherein the optical pathlength of the sample cell is less than about 100  $\mu\text{m}$ .

67. The method of Claim 62, wherein the optical pathlength of the sample cell is less than about 80  $\mu\text{m}$ .

68. The method of Claim 62, wherein the optical pathlength of the sample cell is between about 1  $\mu\text{m}$  and about 50  $\mu\text{m}$ .

69. The method of Claim 62, wherein the optical pathlength of the sample cell is between about 15  $\mu\text{m}$  and about 35  $\mu\text{m}$ .

70. The method of Claim 62, wherein the sample element further comprises an opening in fluid communication with the sample cell, and wherein the slicing step is performed proximate the opening.

71. The method of Claim 62, further comprising filtering the emitted radiation beam to transmit at least the spectral band of radiation.

72. The method of Claim 71, wherein the filtering is performed by a tunable filter.

73. The method of Claim 71, wherein the filtering is performed to transmit radiation between about 0.8  $\mu\text{m}$  and about 2.5  $\mu\text{m}$ .

74. The method of Claim 71, wherein the filtering is performed to transmit radiation between about 2.5  $\mu\text{m}$  and about 20  $\mu\text{m}$ .

75. The method of Claim 71, wherein the filtering is performed to transmit radiation between about 20  $\mu\text{m}$  and about 100  $\mu\text{m}$ .

76. The method of Claim 71, wherein the filtering is performed to transmit radiation between about 3.5  $\mu\text{m}$  and about 14  $\mu\text{m}$ .

77. The method of Claim 71, wherein the filtering is performed to transmit radiation at least at about one of the following center wavelengths: 4.2  $\mu\text{m}$ , 5.25  $\mu\text{m}$ , 6.12  $\mu\text{m}$ , 7.4  $\mu\text{m}$ , 8.0  $\mu\text{m}$ , 8.45  $\mu\text{m}$ , 9.25  $\mu\text{m}$ , 9.65  $\mu\text{m}$ , 10.4  $\mu\text{m}$ , 12.2  $\mu\text{m}$ .

78. A method for reagentless whole-blood analyte detection that can be performed near a patient comprising:

providing a source configured to emit electromagnetic radiation, an optical detector positioned in an optical path of the radiation, a portable housing configured to house at least partially the source and the optical detector, and a sample element containing a sample of whole-blood, the sample element situated in the optical path of the radiation;

emitting an emitted beam of electromagnetic radiation from the source; and

detecting a transmitted beam of radiation that is transmitted through the sample of whole-blood to assess at least one constituent of the sample of whole-blood.

79. The method Claim 78, wherein the sample element is configured to be advanced into the housing.

80. The method Claim 78, wherein the sample element is oriented about vertically.

81. The method Claim 78, wherein the sample element is oriented about horizontally.

82. The method Claim 78, wherein the constituent is glucose.

83. A method of operating a reagentless whole-blood analyte detection system capable of being deployed near a patient, the whole-blood system having an optical calibration system and an optical analysis system, the method comprising:

inserting a sample element comprising a calibration portion and an analysis portion having a sample of whole-blood into the whole-blood analysis system; and

transmitting a first beam of electromagnetic radiation through the analysis portion of the sample element to determine an optical property of the sample of whole-blood and the sample element.

84. The method of Claim 83, further comprising transmitting a second beam of electromagnetic radiation through the calibration portion of the sample element to determine an optical property of the sample element.

85. The method of Claim 84, wherein the step of transmitting the first beam and the step of transmitting the second beam are performed about at the same time.

86. The method of Claim 85, wherein the step of transmitting the first beam and the step of transmitting the second beam are performed contemporaneously.

87. The method of Claim 85, wherein the step of transmitting the first beam is performed before the step of transmitting the second beam.

88. The method of Claim 85, wherein the step of transmitting the first beam is performed after the step of transmitting the second beam.

89. An automatic reagentless whole-blood analyte detection system comprising:  
a source capable of generating radiation comprising at least one wavelength of electromagnetic radiation;

an optical detector positioned in the optical path of the radiation responsive to the radiation to generate at least one signal;

a sample extractor configured to draw a sample of fluid from a portion of tissue;

a sample cell situated in the optical path of the radiation and configured to receive the sample of fluid; and

a signal processor that processes the signal;

wherein the testing system is configured to draw the sample of fluid, to receive the sample of fluid, to generate the radiation, to detect the radiation, and to process the signal without any intervention from the patient.

90. The automatic whole-blood system of Claim 89, wherein the sample extractor is selected from the group consisting of: a lance, laser lance, single-motion lance, iontophoretic sampler, gas-jet, fluid-jet or particle-jet perforator.

91. The automatic whole-blood system of Claim 89, further comprising:  
a housing configured to house at least partially at least one of the source, the optical detector, the sample extractor, the sample cell, and the signal processor.

92. The automatic whole-blood system of Claim 91, wherein the sample cell is configured to be advanced into the housing.

93. The automatic whole-blood system of Claim 91, wherein the sample cell is oriented about vertically.

94. The automatic whole-blood system of Claim 91, wherein the sample cell is oriented about horizontally.